UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,701	05/05/99	DEBOUCK C	P50572

020462 HM22/0411
SMITHKLINE BEECHAM CORPORATION
709 SWEDELAND ROAD P O BOX 1539
KING OF PRUSSIA PA 19406-0939

EXAMINER	
SOUAYA, J	
ART UNIT	**PAPER NUMBER**
1655	9

DATE MAILED: 04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/297,701	Applicant(s) Debrouck et al
	Examiner Jehanne Souaya	Group Art Unit 1655

☒ Responsive to communication(s) filed on *Jan 24, 2001* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-12* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on January 4, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/297,701 is acceptable and a CPA has been established. An action on the CPA follows.

2. Currently claims 1-12 are pending in the instant application. All the have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 are indefinite in the recitation of "similar insertional..." as it is unclear what the claimed element is similar to.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bascomb et al (EPO 0 680 722 A1) and Quandt et al (Gene, 1993, vol. 127, pp 15-21), in view of Lennon et al (Trends in Genetics, October 1991, vol. 7, pp 314-317).

Bascomb teaches that the invention pertains to novel protocols for the screening and rapid identification of compounds that specifically inhibit a predetermined enzyme or metabolic target site that is specific to plants. Bascomb teaches that the enzymatic pathways targeted by the novel screening protocols are unique to plants, bacteria and fungi. Bascomb teaches methods of screening for detection of herbicides (abstract) involving formation of microbes containing genes essential for plant growth and screening for compounds that inhibit plant enzymes (page 4, lines

4-5). Bascomb teaches expressing in a microbial strain a plant gene encoding an essential plant product that enables the microbial strain to grow in the absence of a nutritional supplement otherwise required for growth of the microbial strain, maintaining the microbial strain under conditions suitable for growth of the microbial strain expressing the essential plant gene product, but unsuitable for growth of the microbial strain in the absence of the essential plant gene product, and identifying a compound that inhibits growth of the microbial strain. Additionally, Bascomb teaches that once a herbicidal compound is identified, plant populations may be mutagenized and grown in the presence of the herbicide at a concentration known to be sufficient to inhibit growth of the wild type and then plants that are able to grow can be selected (page 4, lines 13-17, and lines 36-43). Bascomb teaches compositions of herbicides (page 18, lines 1-30) and isolated genes and proteins known to be essential to the growth of plants (page 2, lines 43, page 18, line 51-58). Although Bascomb does not teach such a method in detecting genes essential to the growth of a single celled organism, one of ordinary skill in the art would recognize that such a method could be used to screen for essential genes in microorganisms because Bascomb teaches that the enzymatic pathways target by the novel screening protocols are unique to plants, bacteria and fungi. One of ordinary skill in the art would be motivated to screen for essential genes in single celled organisms for the purposes of screening for possible inhibitors of pathogens. Although Bascomb does not teach the use of suicide vectors in mutagenizing, Quandt teaches the construction of a set of vector plasmids which greatly facilitate gene replacement and reverse genetics in many Gram-negative bacteria (see abstract). Quandt teaches that these vectors,

termed suicide vectors, were used to carry out gene replacement experiments in the fixN region of Rhizobium leguminosarum (see abstract). Quandt teaches using these vectors in the genetic analysis of a wide range of gram negative bacteria and further teach that these vectors offer a number of improvements on existing sacB-based systems which include the ease of cloning fragments into these vectors and the fact that they are mobilisable (see p. 19, col 2 "conclusion"). Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures (see abstract). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the suicide vectors for the purpose of mutagenizing in the modified method of Bascomb as Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures.

Although Bascomb does not teach the use of a grid immobilized library to perform the screening of mutants, Lennon et al teach method of screening libraries involving generating a plurality of filters that form a grid, each grid containing at a predefined region, immobilized cDNA clones (page 314, col. 2, first para, page 315, col. 1 last para, and col. 2). Lennon also teaches the use of a "genomic" cDNA library (p. 314, col. 2, last para). Lennon teaches screening the filters with a labeled hybridization probe to, for example, identify cDNAs (equivalent to mRNAs) that are differentially expressed between tissues and/or developmental stages or directly comparing two sets of conditions (Table 1, page 316, col. 2, first full para). Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods (p 315, col. 2, last para).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the hybridization based screening method of Lennon to have screened for mutations in a population grown under defined conditions (eg. Concentration of herbicide) as taught by Bascomb to have obtained the invention as a whole. One of ordinary skill in the art at the time of the invention would have been motivated to have used the methods of Lennon for screening to have screened for herbicide resistance as taught by Bascom because Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods. The ordinary artisan would have been motivated to screen for potential herbicides because Bascomb teaches such a method would be advantageous in herbicide development. Thus addition of the method of screening of Lennon to perform the method of Bascomb would have made the screening method of Bascomb easier to perform.

7. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al (JBC, March 1994, vol. 269, pp 6320-6324) in view of Lennon et al (Trends in Genetics, October 1991, vol. 7, pp 314-317).

Nishi et al teaches an agent (LMB) that induces arrest of the eukaryotic cell cycle (abstract, fist para of p. 6320). Nishi teaches screening genomic library of LMB-resistant mutants to identify the target gene of LMB (abstract, p. 6320, last para). Nishi teaches comparison of allelic mutation and wild-type (p. 6322, col. 2, fist full para). Nishi teaches the gene and protein

sequence of the LMB resistant gene (p. 6322, Table II). Nishi teaches compositions of the agent LMB (figure 1). Although Nishi does not teach such a method in detecting genes essential to the growth of a single celled organism, one of ordinary skill in the art would recognize that such a method could be used to screen for essential genes in microorganisms. One of ordinary skill in the art would be motivated to screen for essential genes in single celled organisms for the purposes of screening for possible inhibitors of pathogens. Although Nishi does not teach the use of suicide vectors in mutagenizing, Quandt teaches the construction of a set of vector plasmids which greatly facilitate gene replacement and reverse genetics in many Gram-negative bacteria (see abstract). Quandt teaches that these vectors, termed suicide vectors, were used to carry out gene replacement experiments in the fixN region of Rhizobium leguminosarum (see abstract). Quandt teaches using these vectors in the genetic analysis of a wide range of gram negative bacteria and further teach that these vectors offer a number of improvements on existing sacB-based systems which include the ease of cloning fragments into these vectors and the fact that they are mobilisable (see p. 19, col 2 "conclusion"). Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures (see abstract). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the suicide vectors for the purpose of mutagenizing in the modified method of Nishi as Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures.

Although Nishi does not teach the use of arid immobilized library to perform the screening of mutants, Lennon et al teach method of screening libraries involving generating a plurality of filters that form a grid, each grid containing at a predefined region, immobilized cDNA clones (page 314, col. 2, first para, page 315, col. 1 last para, and col. 2). Lennon also teaches the use of a "genomic" cDNA library (p. 314, col. 2, last para). Lennon teaches screening the filters with a labeled hybridization probe to, for example, identify cDNAs (equivalent to mRNAs) that are differentially expressed between tissues and/or developmental stages or directly comparing two sets of conditions (Table 1, page 316, col. 2, first full para). Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods (p 315, col. 2, last para).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the hybridization based screening method of Lennon to have screened for LMB mutations in a population grown under defined as taught by Nishi to have obtained the invention as a whole. One of ordinary skill in the art at the time of the invention would have been motivated to have used the methods of Lennon for screening to have screened for LMB target genes as taught by Nishi because Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods. Thus addition of the method of screening of Lennon to perform the method of Nishi would have made the screening method of Nishi easier to perform.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
April 5, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
4/9/01